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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,380	10/13/2005	Per Gisle Djupesland	44508-149	2677

21890 7590 04/25/2007

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EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	**PAPER NUMBER**
3771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

H1

Office Action Summary	Application No.	Applicant(s)	
	10/520,380	DJUPESLAND, PER GISLE	
	Examiner	Art Unit	
	Kristen C. Matter	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/13/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,52 and 67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26,52 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the present case, Applicant uses the term "comprising", which is considered claim language that should be avoided in the abstract.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Applicant is strongly encouraged to add appropriate headers to the disclosure.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, and 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 5, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. Examiner suggests deleting "such as" from the claim.

Claim 6 is dependent on claim 5 and is therefore rejected for the reasons outlined above with respect to claim 5.

Claims 19 and 21 recite the limitation "the mouthpiece". There is insufficient antecedent basis for this limitation in the claim. Examiner assumes Applicant is referring to the nosepiece.

Claims 20 and 22-23 are dependent on claims 19 and 21, respectively, and are therefore rejected for the reasons outlined above with respect to claims 19 and 21.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 3, 4, 7, 8, 52, and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Fuchs et al. (US 6,708,846).

Regarding claims 1, 52, and 67, Fuchs et al. disclose a dispenser comprising an interface unit (11) including a nosepiece and a nozzle (see Figure 1), a delivery unit with a substance supply (i.e., piercing chamber 13), and an actuation unit (i.e., button 39 that drives spring 109 to move the needle in Figure 18).

Regarding claim 2, Fuchs et al. discloses that the device is disposable (abstract).

Regarding claim 3, the interface unit comprises a single integral unit (Figure 1).

Regarding claim 4, Fuchs et al. disclose that the nozzle assemblies are stored in a reserve holder (149) until needed (Figure 43).

Regarding claims 7 and 8, Fuchs et al. disclose a substance pump for delivering a liquid (column 2, line 33) including a chamber and a piston member moveable in the chamber to deliver a flow of substance.

Claims 1, 2, 3, 7, 52, and 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Mazzoni (US 2004/0153033).

Regarding claims 1, 52, and 67, Mazzoni discloses a dispenser comprising a replaceable interface unit (49) including a nosepiece and a nozzle (see figure 5), a delivery unit with a substance supply unit (i.e., piercing capsule), and an actuation unit (i.e., button 45 that drives spring/piston 8).

Regarding claim 2, Mazzoni discloses that the interface unit is disposable (paragraph 0087).

Regarding claim 3, the interface unit disclosed by Mazzoni is a single integral unit (103).

Regarding claim 7, Mazzoni discloses a substance pump including a chamber containing substance and a piston member that is moveable in the chamber to deliver a flow of substance (Figure 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al.

Regarding claim 9, Fuchs et al. does not disclose a powder substance. It would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have dispensed a liquid or powder depending on the condition the device was being used to treat.

Regarding claim 26, the device disclosed by Fuchs et al. has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing Fuchs et al.'s device, to perform the recited method steps of the instant claim.

Claims 4, 8, 9, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzoni.

Regarding claim 4, Mazzoni is silent as to the interface units being packaged in protective packaging. However, it is considered obvious to one of ordinary skill in the art at the time of the invention to package pharmaceutical dispensers in protective packaging for sanitary reasons.

Regarding claims 8 and 9, Mazzoni is silent as to the type of medicament dispensed. It would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have dispensed a liquid or powder depending on the condition the device was being used to treat.

Regarding claim 26, the device disclosed by Mazzoni has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing Mazzoni's device, to perform the recited method steps of the instant claim.

Claims 1, 2, 12, 15, 16, 17, 18, 19, 20, 21, 22, 23, 26, 52, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brooker et al. (US 6,269,810) in view of Farr (US 3,802,431).

Regarding claims 1, 2, 52, and 67, Brooker et al. discloses a nasal delivery device comprising an interface unit including at least one nosepiece (column 2, lines 43-46), at least one delivery unit including a substance supply unit (19), and an actuation unit (control unit that drives the dosing system). Brooker et al. is silent as to the interface unit being replaceable. Farr discloses a nasal cannula with a nozzle that is disposable (column 2, lines 5-10 and figures). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a disposable nasal cannula for delivering gas to a patients nostrils as taught by Farr in the device disclosed by Brooker et al. for sanitary purposes.

Regarding claims 12 and 15, Brooker discloses air supply line 11(column 6, lines 50-55). The gas supply unit can be considered as either part of the "delivery unit" or the "actuation" unit.

Regarding claims 16 and 17, Brooker et al. disclose that the gas supply is programmed to be synchronous with the patient's exhaled breath and that one or more exhalations can be provided before pulsing substance delivery to the patient (see column 6, lines 50-70).

Regarding claims 18 and 19, Brooker et al. discloses a pressure switch to detect exhalation by the patient and a control unit for driving delivery of the substance upon determination of exhalation (column 6, lines 50-70).

Regarding claim 20, Brooker et al. does not disclose a flow sensor. However, It would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have used a flow sensor in place of the pressure sensor for determining

exhalation because flow sensors and pressure sensors detect substantially the same measured component, and it appears as though the device disclosed by Brooker et al. would have performed equally well with either a flow sensor or a pressure sensor for sensing exhalation.

Regarding claim 21, the number of exhalations can be considered a trigger mechanism for actuating the delivery unit.

Regarding claims 22 and 23, although Brooker does not explicitly disclose a predeterminable pressure or flow rate, in order to detect exhalation the control system must have some sort of predetermined pressure or flow rate considered to constitute an exhalation (i.e., negative flow), and since the drive unit is actuated in response to exhalation by the patient, the derive could also be said to be actuated in response to a predetermined pressure or flow rate in the interface unit.

Regarding claim 26, the modified device disclosed by Brooker et al. has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the modified device, to perform the recited method steps of the instant claim.

Claims 1, 10, 11, 12, 13, 14, 15, 24, 25, 26, 52, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curti et al. (US 2006/0174886) in view of Patton et al. (US 6,681,767).

Regarding claims 1, 10, 52, and 67, Curti et al. discloses a delivery device including a nasal cannula with nozzles (5', 7') and a mouthpiece (9') into which a user exhales (paragraph 0012) and at least one delivery unit (210) for delivering a substance supply (abstract). To the

extent that Curti et al. is silent as to the specifics of the delivery unit and an actuation unit for actuating the delivery unit of the interface unit, Patton et al. discloses a device for delivering a supply to a user comprising a substance supply with a controller for actuating a supply of gas or a fixed amount of liquid propellant to the dispersing device (see column 5, lines 5-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a delivery system as taught by Patton et al. in the device disclosed by Curti et al. for delivering aerosolized medicament to a user.

Regarding claim 11, Curti et al. discloses a flow path communicating with both a first nostril and a mouth of the patient (paragraph 0016).

Regarding claims 12 and 15, the modified Curti et al. device has a gas supply line (208). The gas supply unit can be considered as either part of the "delivery unit" or the "actuation" unit.

Regarding claim 13, Patton et al. discloses that the gas supply can be any of a pump, a cylinder, a piston pump, etc. (column 6, lines 15-25). Using a gas pump with a cylinder and moveable piston is a matter of design consideration to one of ordinary skill in the art.

Regarding claim 14, Patton et al. discloses that the device can be used with pulsating delivery units which pulse a substance supply into a gas supply that has been previously actuated.

Regarding claim 24, Curti et al. disclose first and second nosepiece units and first and second delivery units each including a substance supply (Figure 16C).

Regarding claim 25, although Curti et al. is silent as to the delivery units being operated in succession, the disclosed device has all of the structural limitations of claim 25 and is fully capable of operating the delivery devices in succession due to the independent flow paths.

Regarding claim 26, the modified device disclosed by Curti et al. has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the modified device, to perform the recited method steps of the instant claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7-23, 26, 52, and 67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/469,114. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claim and the instant claim are minor and obvious from each other. The instant claims 1, 52, and 67 are

a broader version of the copending claim 1 (i.e. the instant claim 1 does not include the structural element of the mouthpiece as in the copending claim 1). In the instant claims 1, 52, and 67 the structural elements are included in the copending claim 1. Although the copending claim does not explicitly state that the interface unit is a replaceable unit, it is considered to have been obvious to one of ordinary skill in the art at the time of the invention to make the interface unit replaceable for sanitary purposes. Therefore, any infringement over the copending application would also infringe over the instant claim. Hence, the instant claims do not differ from the scope of the copending claim 1. A similar argument is applied to instant claim 26 with regards to copending claim 17.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 7-23, 26, 52, and 67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/469,105. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claim and the instant claim are minor and obvious from each other. The instant claims 1, 26, 52, and 67 are a broader version of the copending claim 1 (i.e. the instant claim 1 does not include the structural elements of the mouthpiece or breath analyzer as in the copending claim 1). In the instant claims 1, 52, and 67 the structural elements are included in the copending claim 1. Although the copending claim does not explicitly state that the interface unit is a replaceable unit, it is considered to have been obvious to one of ordinary skill in the art at the time of the

invention to make the interface unit replaceable for sanitary purposes. Therefore, any infringement over the copending application would also infringe over the instant claim. Hence, the instant claims do not differ from the scope of the copending claim 1. A similar argument is applied to instant claim 26 with regards to copending claim 18.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 10, 26, 52, and 67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 32 of copending Application No. 10/489,187. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claim and the instant claim are minor and obvious from each other. The instant claims 1, 26, 52, and 67 are a broader version of the copending claims 1 and 32 (i.e. the instant claims do not include the structural elements of the mouthpiece or release mechanism as in the copending claims 1 and 32). In the instant claims 1, 26, 52, and 67 the structural elements are included in the copending claims 1 and 32. Although the copending claim does not explicitly state that the interface unit is a replaceable unit, it is considered to have been obvious to one of ordinary skill in the art at the time of the invention to make the interface unit replaceable for sanitary purposes. Therefore, any infringement over the copending application would also infringe over the instant claim. Hence, the instant claims do not differ from the scope of the copending claims 1 and 32. With regards to claim 26, because the copending claim has all of the structural limitations and is fully capable of performing the recited method steps, it would have been obvious to one of

ordinary skill in the art at the time the invention was made, upon seeing the copending claim device, to have performed the instant claim method steps.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 10, 26, 52, and 67 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 34 of copending Application No. 10/586,391. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the copending claim and the instant claim are minor and obvious from each other. The instant claims 1, 26, 52, and 67 are a broader version of the copending claim 34 (i.e. the instant claim 1 does not include the structural elements of the mouthpiece or release mechanism as in the copending claim 34). In the instant claims 1, 26, 52, and 67 the structural elements are included in the copending claim 34. Although the copending claim does not explicitly state that the interface unit is a replaceable unit, it is considered to have been obvious to one of ordinary skill in the art at the time of the invention to make the interface unit replaceable for sanitary purposes. Therefore, any infringement over the copending application would also infringe over the instant claim. Hence, the instant claims do not differ from the scope of the copending claim 34. With regards to claim 26, because the copending claim has all of the structural limitations and is fully capable of performing the recited method steps, it would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the copending claim device, to have performed the instant claim method steps.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 5 and 6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Riggs et al. is cited to show a powder nebulizer which could be used in the cited systems, Davison is cited to show another gas pump delivery device, and Gonda et al. and Ohki et al. are cited to show other relevant nasal delivery devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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4/20/07